Rec'd 1/7/81

MEMORANDUM OF TELEPHONE CONVERSATION
December 10, 1980

BETWEEN: Jim Allen
Senior Chemist
National Pharmaceutical Mfg. Co.
Baltimore, Maryland 21207
(301) 298-1000

and

Gerald M. Rachanow
Deputy Director
Division of OTC Drug Evaluation

SUBJECT: Decision on Dosage of Pseudoephedrine Preparations

I called Mr. Allen in response to his letter of November 25, 1980 to Dr. Gilbertson concerning the decision on the dosage of pseudoephedrine preparations. I informed him that it appeared that the effective date for the required relabeling would be extended until May 1, 1981; that a notice was being prepared for publication in the FEDERAL REGISTER. I stated that I would send him a copy as soon as it was published.

I explained that FDA had not taken a position on the recommendations of the Cough-Cold Panel on combination products containing pseudoephedrine, but that in the interim his company could continue to follow the Panel's dosage recommendations. I explained that most combinations are covered by the Panel's dosage recommendations of an every 4 to 6 hour dosage for almost all cough-cold ingredients. I pointed out that in a few cases reformulation and additional stability testing might be necessary where it is necessary to increase the amount of drug in a product to obtain an every 6 hour dose, e.g., dextromethorphan.

I told Mr. Allen we would respond to his letter in writing once the notice extending the effective date is published. He thanked me for calling and for the information provided.

Gerald M. Rachanow

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